



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/664,679

09/16/2003

Barry O'Brien

10527-462001

4092

26161 7590 06/18/2008

FISH & RICHARDSON PC  
P.O. BOX 1022  
MINNEAPOLIS, MN 55440-1022

EXAMINER

NGUYEN, VI X

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

06/18/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/664,679	<b>Applicant(s)</b> O'BRIEN ET AL.	
	<b>Examiner</b> Victor X. Nguyen	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 47-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-31 and 49-56 is/are rejected.
- 7) ☒ Claim(s) 47,48 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5,11,12,15-21,24-28,31,49-50 and 55-56 rejected under 35 U.S.C. 103 (a) as being unpatentable over Buscemi et al. (5,769,883) in view of Yan (5,843,172).

Buscemi discloses a stent device having the limitations as recited in the above listed claims, including: a tubular member which includes a porous structure (fig. 6, lines 27-30), where the porous structure defined by a plurality of hollow post shaped elements at 118, where the hollow post shaped elements separated by a void region at 105 and each hollow post shaped element defines an internal volume at 119 which adapted to contain a therapeutic agent (see col. 11, lines 34-37).

Buscemi is silent regarding the porous structure comprising of titanium or tantalum or an alloy thereof.

Yan discloses the porous structure comprising of titanium or tantalum or an alloy thereof (see col. 4, lines 14-47)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Buscemi by constructing the porous structure comprising of titanium or tantalum or an alloy thereof as taught by Yamauchi for improving the strength and elasticity of making a stent with porosity of the metal, because one of

Art Unit: 3734

ordinary skill in the art would have been able to carry out such a substitution, and the results were reasonably predictable.

As to claims 2-5,11-12,15-21,24-28,31,49-50,55-56, Yan discloses (see col. 2 lines 46-66 and col.4, lines14-47 and col. 5, lines 1-54) the tubular member comprises a therapeutic agent contained in the internal volumes, the void (see figs. 6, 8) which is selected from an antithrombogenic or antibiotic drug, where the porous structure includes a polymer which is coating over the structure, and where the porous structure is inherently including a colorant which enable the device to be visualized during implantation (see col.7, lines 21-50), and where the hollow post shaped element generally tubular which comprises a closed end as disclosed in fig. 8 of Buscemi.

Regarding claims 6-10,13-14,22-23 and 29-30, Buscemi in view of Yan discloses the device substantially as claimed except for the tubular member includes a layer that has a thickness between 50nm and about 500nm and the post shaped elements have pore diameters of about 20nm-200nm or a post height of about 100nm-200nm. It would have been obvious to modify the tubular member includes a layer that has a thickness between 50nm and about 500 nm and the post shaped elements have pore diameters of about 20nm-200nm or the post height of about 100nm-200nm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re. Aller, 220F, 2d 454, 105 USPQ 233. Furthermore, Buscemi in view of Yan is silent regarding the different metal is about 90% or more of the thickness of the tubular member or the device has a color corresponding to light having a wavelength between 370 nm –750 nm.

Art Unit: 3734

It would have been obvious to modify the different metal is about 90% or more of the thickness of the tubular member or the device has a color corresponding to light having a wavelength between 370 nm –750 nm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re. Aller, 220F, 2d 454, 105 USPQ 233.

Regarding claims 51-54 , Buscemi in view of Yan discloses the device substantially as claimed except for the post shaped porous structure element has density of 10- 300 post-shaped elements per square micron. It would have been obvious to modify the post shaped porous structure element has density of 10- 300 post-shaped elements per square micron, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re. Aller, 220F, 2d 454, 105 USPQ 233. Furthermore, Buscemi in view of Yan is silent regarding the porous structure acts as a grating that preferentially reflects light having a wavelength between 370 nm and 750 nm. It would have been obvious to modify the porous structure acts as a grating that preferentially reflects light having a wavelength between 370 nm and 750nm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re. Aller, 220F, 2d 454, 105 USPQ 233.

***Allowable Subject Matter***

2. Claims 47-48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

***Response to Arguments***

3. Applicant's arguments filed 2/11/2008 have been considered but they are not persuasive. In response to applicant's argument that neither Buscemi nor Yan disclosed the claimed "porous structure defined by a plurality of hollow post shaped elements, the hollow post shaped elements separated by a void region therebetween and each hollow post shaped element defining an internal volume adapted to contain a therapeutic agent". The examiner disagrees. It is noted that Buscemi teaches a tubular member which includes a porous structure (fig. 6, lines 27-30), where the porous structure defined by a plurality of hollow post shaped elements at 118 (these delineates pores 118 are considered as post shaped because it has a piece that is fixed firmly in an upright position as a support or a bridge). The examiner recommends further description of the hollow post shaped element structure to overcome the prior art, where the hollow post shaped elements separated by a void region at 105 (the voids 105 are throughout the body of the stent, therefore, it would configure to occur between a plurality of hollow post shaped elements) and each hollow post shaped element defines an internal volume at 119 which adapted to contain a therapeutic agent (see col. 11, lines 34-37).

***Conclusion***

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

Art Unit: 3734

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ho Jackie can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/  
Primary Examiner, Art Unit 3734

Victor X Nguyen  
Examiner  
Art Unit 3734

VN  
6/16/2008